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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,354	03/16/2004	Laurence M. Shanley	F-8181	3618

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/802,354	Applicant(s) SHANLEY, LAURENCE · M.	
	Examiner Laura A. Bouchelle	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al (US 5201721). Lee discloses a safety needle comprising a receiver 20, a protective cap 28, the receiver being movably disposed in the protective cap from a closed position to a functional position. The receiver has a tab 26 that corresponds to a groove 38 in the inner jacket surface of the cap. The device is a syringe and a hypodermic needle. See Figs. 1-3.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 1, 4, 5, 9, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Stehrenberger et al (US 5269761).
5. Claims 1, 5 differ from Lee in calling for the cap to have a guide for the needle. Stehrenberger teaches a safety needle having a cap assembly 12 having a guide portion 26 that

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allows the needle to pass when the cap is retracted while still covering the needle seat and protect the needle when it is in the extended position (Col. 3, lines 6-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lee to include a guide on the cap as taught by Stehrenberger so that the needle is protected in the extended position and the needle protrudes in the retraced position, but the needle seat remains covered.

6. Claims 2, 3, 7, 8, are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Stehrenberger as applied to claims 1, 5 above, and further in view of Grabis et al (US 6322540). Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Grabis. Claims 2, 7, 15 differ from Lee in calling for a clip ring. The limitations of claims 3 and 8 are disclosed by Lee as discussed above. Grabis teaches a safe needle device comprising a protective cover 7 and a ring 11 that acts as a stop to prevent motion of the receiver past a certain point on the cover. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lee in view of Stehrenberger to include a ring as taught by Grabis so that the cover does not inadvertently move too far in one direction past the receiver.

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Stehrenberger as applied to claim 5 above, and further in view of Olovson (US 2002/0193749). Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Olovson.

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Claims 6, 13 differ from Lee in view of Stehrenberger in calling for a membrane to seal the opening when the cover is in a closed position. Olovson teaches a needle protector 2' comprising a membrane 2b that seals off the opening of the protector while in the closed position to prevent contamination of the needle prior to use (Page 4, paragraph 0075). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Lee in view of Stehrenberger to include a membrane as taught by Olovson to prevent contamination of the needle prior to use.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Stehrenberger in view of Grabis as applied to claim 3 above, and further in view of Gregorio (US 5346475). Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee in view of Gregorio. Claims 11, 13 differ from the teachings above in calling for the cap to define at least two functional positions. Gregorio teaches a syringe having a cap 28 that is capable of locking in multiple positions such that the needle projects out of the front of the cap by varying amounts. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device above to include a cap capable of locking in more than one functional position as taught by Gregorio so that the needle can project out of the front of the cap by varying amounts.

Response to Arguments

9. Applicant's arguments filed 10/2/06 have been fully considered but they are not persuasive. Applicant argues that the cap of Lee does not completely encase the sharps element.

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Examiner defines encase to mean enclose or surround as with a fence or wall. The cap of Lee fits this definition. However, the examiner believes that the amendments to the claims have made this point moot.

10. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the current device is separately attached to the syringe and does not compromise the syringe or syringe barrel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Laura A Bouchelle
Examiner
Art Unit 3763

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